

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
AT CHARLOTTESVILLE**

**KAIA VICTORIA KRISTENSEN, a
minor by next friend, SUSAN LEIGH
KRISTENSEN,**

Plaintiff,

v.

**WILLIAM DAVID SPOTNITZ and
DENISE CONSTANCE SCHAIN,**

Defendants.

**Case No.: 3:09CV00084
(consolidated with 3:09CV00085)**

**DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION IN LIMINE TO
EXCLUDE DR. LEONARD VANCE, DR. JOSEPH VILSECK, DR. RICHARD LIPSEY,
DR. ELIZABETH FRYE, AND DR. ANDREW ELGORT**

COME NOW before the Court, the defendants, by counsel, and moves to exclude the expert opinions proffered by Dr. Leonard Vance, Dr. Joseph Vilseck, Dr. Richard Lipsey, Dr. Elizabeth Frye, and Dr. Andrew Elgort as unreliable, unfounded, and irrelevant under Daubert v. Merrell Dow Pharms., 509 U.S. 579, 592-93 (1993) and Federal Rule of Evidence 702.

ARGUMENT

In order to prove causation in a toxic exposure case, like the case at hand, the plaintiffs must prove via expert opinion to “identify a dose-response relationship for a particular chemical (or chemical mixture) and illness and analyze the results to determine whether the duration and concentration of exposure in a given instance could have caused the alleged harms.” Cavallo v. Star Enter., 892 F. Supp. 756, 764 (E.D. Va. 1995). To prove a dose-response relationship, a two part analysis must be conducted. McCallum v. United States, 2005 U.S. Dist. LEXIS 7998, 26-27 (D. Va. 2005). First, a plaintiff must prove that a particular agent is harmful to human beings

generally, also known as general causation. Id. Second, a plaintiff must establish that exposure to the potentially harmful agent actually caused his condition, known as specific causation. Id.

With this general framework in mind, the Court must analyze whether the proffered experts' opinions are reliable and relevant under Rule 702 of the Federal Rules of Evidence and Daubert. Rule 702 serves as the district court's "gatekeeping" function as set forth in Daubert. Rule 702 provides that

Testimony by Experts -- If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The proponent of the proposed expert testimony must establish its admissibility by a preponderance of proof. See Daubert, 509 U.S. at 592 n.10; Fed. R. Evid. 104(a).

In Daubert, the United States Supreme Court charged trial judges with the responsibility to act as "gatekeepers" to "ensure that any and all scientific testimony . . . is not only relevant, but reliable." Daubert, 509 U.S. at 589. In conducting its analysis, the trial court is to determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Id. at 592. The trial court is to initially assess "whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 592-93. The first prong looks to reliability of the expert's opinion, whether the opinion has a reliable basis in the knowledge and experience of the particular field. Id. at 590-591. It is insufficient if the opinion is a "subjective belief or unsupported by speculation." Id. at 590.

The Daubert Court set forth a non-exhaustive checklist of factors for trial courts to use to determine the reliability prong. Id. at 593-94. The factors are as follows: (1) whether a theory or technique underlying the opinion can be or has been tested; (2) whether the technique has a known potential rate of error and the existence and maintenance of standards controlling the technique's operation; (3) whether the theory or technique has been subjected to peer review and publication; (4) whether the expert's theory or technique enjoys "general acceptance" within a relevant scientific community. Id. at 592-94. Other factors have been identified by other courts. In Ervin v. Johnson, the Seventh Circuit considered whether the expert's testimony is based on sufficient facts or data. 492 F.3d 901, 904-05 (7th Cir. 2007). The Supreme Court, in Kumho Tire Co. v. Carmichael, stated that the trial court can consider other factors when appropriate to ensure that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." 526 U.S. 137, 152 (1999). Another factor to consider is whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give. Id. at 151; see also Moore v. Ashland Chemical, Inc., 151 F.3d 269 (5th Cir 1998)(clinical doctor was properly precluded from testifying to the toxicological cause of the plaintiff's respiratory problem, where the opinion was not sufficiently grounded in scientific methodology)). An additional factor is whether the expert has properly accounted for the obvious alternative explanations. Claar v. Burlington N.R.R., 29 F.3d 499 (9th Cir. 1994).

The second inquiry of the Daubert analysis turns on whether the expert's testimony will be helpful to the trier of fact in deciding a fact in issue. The question of relevancy has been referred to whether the opinion "fits" the case at hand. Daubert, 509 U.S. at 591. In other words, the opinion must have a valid connection to the specific inquiry before it is admissible. Id. at

591-92. “Not only must each stage of the expert’s testimony be reliable, but each stage must be evaluated practically and flexibly without bright-line exclusionary (or inclusionary) rules.”

Heller v. Shaw Industries, Inc. 167 F.3d 146, 155 (3d Cir. 1999).

I. Dr. Vance’s Opinions are not Grounded in Sufficient Facts or Data and He is Unqualified to Offer a Medical Opinion

Dr. Leonard Vance, an industrial hygienist, opines (i) that excessive moisture was in the subject residence; (ii) that mycotoxins were in the subject residence; (iii) that volatile organic compounds (VOCs) were in the subject residence; and (iv) to the general health effects of mold. Rule 702 would preclude the admission of the first three opinions as they are not “based upon sufficient facts or data.”

In re Bausch & Lomb, Inc. Contact Lens Solution Products Liability Litigation is instructive of why the plaintiffs’ here must offer an opinion supported by a reliable evidentiary basis. 2009 U.S. Dist. LEXIS 83849 (D.S.C. Aug. 26, 2009). The plaintiffs, in In re Bausch & Lomb, argued that the disinfectant lens solution ineffectively killed certain organisms, which increased the likelihood of infection from these microbes. Id. at 33. The court said that it was critical for the plaintiffs to identify a threshold level of microbes that will cause infection because small minorities of wearers get infections even though a sizable majority of lens cases are infected at any given time. Id. at 34. Specifically, the court said that “[i]n the absence of a reliable evidentiary basis to connect any loss of efficacy/increase in the microbial load with causation in humans, plaintiffs’ expert opinions amount to speculation and potentialities.” Id. Ultimately, the court excluded the expert’s general causation opinion due to the failure to identify the hazardous level for microbial infection. Id.

Dr. Vance first opines that there were excessive levels of mold based upon (i) the plaintiffs' reports of mold and (ii) the Sci-Lab reports indicating the presence of mold. Vance Depo. At 11:21-22 attached hereto as Exhibit A. He offers a second opinion that there was excessive water flowing through the skylight. Id. at 14:4-9. The basis for this opinion is the same as his first opinion with the addition of supposed testimony of Dr. Schain and Steve and Berit Prince regarding the leaking skylight. Id. at 14:9-15. The apparent reason for these two opinions is to show that the plaintiffs were exposed to hazardous levels of mold in the home.

However, he acknowledges that mold is ubiquitous and one would expect to find mold in the subject residence. Id. at 14:24-25, 15:1-3. He also states that he cannot define what would be a safe level of mold in the home. Id. at 15:13-15. Moreover, he testified that there is no published data on what a safe level of mold would be. Id. at 15:16-18. Also, plaintiffs can offer no published data or peer reviewed material that sets any harmful threshold. In fact, referring to his previous testimony in the parents' state court action, Dr. Vance testified that "I'm not going to characterize the mold that was present as being a lot of mold or as not being a lot of mold" concerning the same house. Id. at 32:9-11. Even though mold was present in the home, which he would normally expect, Dr. Vance reaches his conclusion without showing that the mold exceeded a dangerous level. A trial court is not required to admit "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997). "[I]t still is a requirement that the expert opinion evidence be connected to existing data by something more than the 'it is so because I say it is so' of the expert." Holesapple v. Barrett, 5 Fed. Appx. 177, 2001 U.S. App. LEXIS 3128 (4th Cir. Md. 2001)(court of appeals affirmed trial court's ruling excluding expert and awarded summary judgment where opinion on the cause of the boat accident did not connect to the existing data).

Here, Dr. Vance is essentially saying that the level of mold in the home was at a dangerous level “because he says so.”

As in the case of In re Bausch & Lomb, the critical piece here to prove causation is that the plaintiffs were exposed to harmful levels of mold, mycotoxins, or VOCs. According to Dr. Vance, mold is everywhere and is expected to be found in the home. Therefore, the plaintiffs must prove that they were exposed to harmful levels. To do so would require Dr. Vance to speculate on what those levels are and that the agent exceeded those levels.

Dr. Vance next opines that there were harmful levels of mycotoxins. Again, Dr. Vance admits that the testing conducted in the house did not test for mycotoxins. Id. at 21:21-24. Despite the absence of any testing, the basis for his opinion is that the molds found in the home (penicillium, stachybotrys, and aspergillus) inevitably produce mycotoxins. Id. at 24:14-18. Penicillium, stachybotrys, and aspergillus refers to the genus classification. Id. at 25:22-25. These molds can be further classified into different species. Id. Dr. Vance can only point to the genus classification, not the species. Id. at 22:19-20. He is unaware whether all of the mold species always produce mycotoxins. Id. at 25:23-25. Because there is no data or facts to indicate which species were present, Dr. Vance cannot pinpoint which mycotoxins were present in the home. Like molds, there is no harmful level or permissible exposure limits for mycotoxins that has ever been published according to Dr. Vance. Id. at 29:4-12. Yet again, plaintiffs cannot offer any peer reviewed material that sets forth a harmful threshold. Regardless of whether mycotoxins were in the house, because there are no published exposure limits, such an opinion would not assist the trier of fact as to whether the plaintiffs were exposed to dangerous levels of mycotoxins.

As to the presence of VOCs, Dr. Vance opines that they were present in the house despite the fact that the testing did not test for VOCs. Id. at 29:2-4. VOCs are present in everyday life, such as cleaning products, rubbing alcohol, paint, oil based paint, and new construction materials. Dr. Lipsey Depo. at 51:14-22, 60:25 – 61:3 attached hereto as Exhibit B. Regardless of their presence, like mold and mycotoxins, there is no published data on safe or harmful exposure limits. Id. at 30:4-12. Again, no peer review material exists on exposure limits. Whether its mold, mycotoxins, or VOCs, the plaintiffs cannot say that the plaintiffs' level of exposure exceeded a safe level and that those safe levels are generally accepted in the scientific community.

Last, Dr. Vance, an industrial hygienist, offers a medical causation opinion despite the fact that he is neither licensed as a medical doctor nor received medical education or training. See Dr. Vance curriculum vitae attached hereto as Exhibit C. Although he claims to only discuss the “general health effects of molds and mold by-products,” such an opinion, nevertheless, is synonymous with a medical causation opinion. Vance Depo. at 33:16-18. In his report dated March 26, 2011, he states that

All molds have the potential to cause health effects, and molds produce allergens, irritants, and in some cases toxins. (internal citation omitted). It is well established that mold and the related moisture exposure conditions can cause irritation of the skin, eyes, throat and upper respiratory tract as well as allergenic reactions. (internal citation omitted). Although all molds are allergic, some types of mold have been long associated with adverse human health effects inside homes.

Vance Report attached hereto as Exhibit D. Simply because Dr. Vance is qualified as an industrial hygienist, he is not qualified to give a medical opinion. “The fact that a proposed witness is an expert in one area, does not *ipso facto* qualify him to testify as an expert in all related areas.” Shreve v. Sears, Roebuck & Co., 166 F. Supp. 2d 378, 391 (D. Md. 2001); Stull v.

_____, 906 F.2d 1271, 1275 (8th Cir. 1990)(mechanical engineer could not testify that human foot would have been broken had lawn mower upturned as plaintiff claimed because he was not an expert on human anatomy). Dr. Vance even concedes that he is not qualified to testify to whether the plaintiffs suffer from these conditions. Vance Depo. at 33:18-20. Therefore, any opinion regarding health effects is unreliable. In addition, Dr. Vance cannot “fit” the “general health effects” to the facts of this case. See Garlinger v. Hardee’s Food Sys., Inc., 16 F. App’x 232, 2001 U.S. App. LEXIS 18559 (4th Cir. 2001)(Despite the fact that the expert’s “testimony about the effects of hot liquids on human skin may have scientific validity in some contexts, it does not ‘fit’ this case.”). Offering an opinion of general health hazards resulting from mold is nothing more than a “scare tactic” to inflame the jury and is irrelevant to the facts of this case.

II. Dr. Vilseck’s Opinions Are Based Upon Unreliable Methodologies, Based Upon Irrelevant Evidence and Do Not Rule Out Alternatives

Dr. Vilseck’s causation opinion testimony should be excluded because it is based upon (i) an improper and unreliable methodology, (ii) science that is not generally accepted in the medical community, and (iii) fails to consider all sources of exposures as part of his diagnosis.

In forming his causation opinion linking mold exposure to the plaintiffs’ alleged injuries, Dr. Vilseck employs a methodology based upon consideration of four factors: (i) the typical immunoglobulin E (IgE) allergy reaction, (ii) the contemporaneous illness of all family members in the subject house, (iii) type of genus of mold known, and (iv) exposure. Dr. Vilseck report attached hereto as Exhibit E; Dr. Vilseck Depo. at 13:10-25 – 16:1-9 attached hereto as Exhibit E. His methodology is based solely upon his experience. Dr. Vilseck Depo. at 19:24-25 – 20:1-9. No evidence exists that his self-created causation methodology has ever been tested. No evidence exists whether his methodology has a known potential rate of error. No evidence exists

whether his methodology has created standards to control its operation. No evidence exists that his methodology has gained “general acceptance” within the medical community.

Choosing to apply his self-created methodology, Dr. Vilseck ignored generally accepted criterion for making a causal connection between an environmental agent and medical conditions. When questioned about his familiarity with Sir Bradford Hill’s or *Bradford-Hill* criterion for infectious agents, Dr. Kenneth J. Rothman, Dr. Tee Guidotti, or the U.S. Surgeon General, he answered that he “read that over,” but does not “know what other people do.” Dr. Vilseck Depo. at 21:12-25 – 22:1-3. In the *Bradford-Hill* causation analysis, the following factors are considered: (i) temporality, (ii) strength of association, (iii) replicability, (iv) dose-response relationship, (v) cession of exposure, (vi) consistency (consistent findings observed by different persons in different places with different samples strengthens the likelihood of an effect), (vii) consistency with the facts in this matter, and (viii) alternatives. Dr. Vilseck fails to “analyze factors such as timing, duration, exposure or dose in relationship to the various health triggering sources or agents when making his causation assessment. The sporadic nature of the manifestation of alleged allergy symptoms is not consistent with their allegations of a chronic and wide spread source or sources within the house.” Dr. Cheung Report attached hereto as Exhibit G. Because Dr. Vilseck used his own causation methodology as opposed to one generally accepted in the medical community, his opinion is both unreliable and unproven.

Not only is his methodology flawed, but Dr. Vilseck fails to rule out other potential causes of the plaintiffs’ alleged reactions. As part of his causation analysis, Dr. Vilseck conducted a differential diagnosis, albeit incorrectly. Dr. Vilseck Depo. at 20:20-25 – 21:1-11. The Eastern District of Virginia has explained what an expert must do when conducting a differential diagnosis.

[A] differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation. . . . Thus, if an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert's testimony.

Perkins v. United States, 626 F. Supp. 2d 587, 594 (E.D. Va. 2009).

When questioned about whether Alexander's respiratory problems were caused by mold or dust mites, Dr. Vilseck was not even aware that Alexander was allergic to dust mites. Dr. Vilseck Depo. at 45:2-12. A skin test conducted by Dr. Rakes of University of Virginia determined that Alexander was allergic to dust mites. See Dr. Rakes Records attached hereto as Exhibit H. Even more compelling, Dr. Vilseck could not explain how he ruled out dust mites and also failed to explain why dust mites were not the sole cause. Again, this important flaw in his testimony indicates that Dr. Vilseck is speculating.

Nevertheless, Dr. Vilseck explains that both children are atopic, meaning "very allergic." Dr. Vilseck Depo. at 87:11. He states that Kaia is allergic to grasses, weeds, mold, cockroach, dust mite, dog, cat, fish, wheat, corn, orange, peanut, and carrot. Id. at 79:10-25 – 80:1-14. Alexander was allergic to oak tree, grasses, several weeds, mold, dust mites, horse, cat, pork, string bean, lamb, lima beans, pineapple, raspberry, spinach, tomato, and apricot. Id. at 57:2-25 – 58:10-17. Yet, he offers no explanation how he ruled out these other allergies as the cause of his and her reactions. Because he cannot rule out all other known allergies, Dr. Vilseck did not properly conduct a differential diagnosis and, therefore, his opinion is unreliable.

Moreover, Dr. Vilseck explains that molds, like *Penicillium* and *Alternaria*, are broken down into species. Dr. Vilseck Depo. at 50:1-14. Different species of one particular mold can result in opposite reactions in a skin test. Id. at 50:10-21. For instance, *Alternaria* may be found in the home, but the person may not be allergic to that species of *Alternaria*. In fact, he

acknowledges that, when conducting the allergy test on the children, he simply took the species of *Alternaria* that was provided by the laboratory. Id. at 58:23-25 – 1-5. Yet, Dr. Vilseck acknowledges that a doctor cannot test for the same mold that was found in the house. Id. at 50:22-23. He further stated that “there are hundreds of species.” Id. at 51:1-3. Because the lab results did not identify the species of mold, Dr. Vilseck could not identify the mold that caused the plaintiffs’ health conditions. Id. at 50:15-21. This flaw is akin to Dr. Vilseck trying to determine if they suffered an allergic reaction to red onions by testing for yellow onions.

It is nearly impossible for Dr. Vilseck to make a proper causation analysis knowing that (i) different species of the same mold can result in opposite reactions and (ii) the laboratory testing of the mold in the home does not specify any or all of the species for each known mold. For this reason, Dr. Vilseck cannot offer an opinion well grounded in fact.

In addition to his flawed causation opinion, Dr. Vilseck also opines that the plaintiffs will develop allergies to mold simply as a result of their exposure. Dr. Vilseck Depo. at 40:20-24, 73:11-20, 106:22-24, 107:5-12. In short, exposure to mold can “sensitize a nonallergenic person.” Id. at 106:22-23. This opinion is based solely on one sentence out of all the medical literature on this topic. See id. at 40:25 – 41:1-9. It reads that “[r]epeated or single exposure to mold or mold spores may cause previously nonsensitive individuals to become sensitive.” Environmental Protection Agency, Mold Remediation in Schools and Commercial Buildings, EPA 402-K-01-001 (March 2001). One sentence does not represent what has been accepted by the greater medical community. Under Dr. Vilseck’s theory, if a person were not allergic to peanuts, but continually ate them, that person would then become sensitized and allergic. Application of common sense and knowledge debunks that theory.

Damp Indoor Spaces, published in 2004 and one of the foremost authorities on mold, says that there is no sufficient evidence of a causal relation between health outcome and exposure to mold or other agents in damp indoor environments. Institute of Medicine of the National Academies, Damp Indoor Spaces, 8-9 (2004)(copies attached hereto as Exhibit I. There is merely an association, not a causal relationship, between mold and sensitized persons. Id. Similarly, the World Health Organization, in 2009, stated that there is insufficient evidence of a causal relationship between indoor dampness-related agents and health outcomes. World Health Organization Indoor Air Quality Guidelines, World Health Organization, 71 (2009) attached hereto as Exhibit J.

In addition, a 2006 American Academy of Allergy, Asthma and Immunology (AAAAI) Report found that

Studies do not conclusively demonstrate a causal relationship of airborne mold exposure and clinical manifestations of allergic rhinitis. The data on outdoor molds (eg, *Alternaria* species and basidiomycetes) purportedly causing allergic rhinitis are indirect and conflicting. Studies attempting to correlate indoor molds with symptomatic allergic rhinitis are even more problematic because of such methodological uncertainties as lack of quantitative mold sampling and inclusion of respiratory tract infections.

Robert K. Bush, The Medical Effects of Mold Exposure, 117 (No. 2) J Allergy Clin Immunol 326, 327 (2006) attached hereto as Exhibit K.

III. Dr. Lipsey is Unqualified to Offer His Medical Causation Opinion and His Opinions on Mycotoxin and Volatile Organic Compound Exposure are Unreliable

Like Dr. Vance, Dr. Lipsey, a toxicologist, is effectively offering a medical causation opinion “[tying] the exposure in the home to all four family members, including [Alexander].” Dr. Lipsey Depo. at 15:12-17. Irrespective of whether he couches the opinion as specific or general causation, Dr. Lipsey testified that he will rely upon the Koch Postulate and *Bradford-Hill* Criteria for making a causation opinion and will opine that the plaintiffs’ symptoms are

consistent with mold exposure. Id. at 16:12-17. He further testified that there “is no more likely cause of his symptoms.” Id. at 16:17-18. He even characterized the plaintiffs’ conditions as a “classic mold poisoning case.” Id. at 16:19-21. Boiled down, Dr. Lipsey will opine that the children had symptoms consistent with mold exposure; therefore, they had mold exposure. This opinion, despite attempting to classify it as a general causation opinion, is nothing less than a specific medical causation opinion.

It is generally understood that when an expert offers a medical causation opinion, the expert must have a medical degree or medical training. See John v. Im, 263 Va. 315, 321, 559 S.E.2d 694, 697; Estate of Hezekiah Harvey v. Roanoke City Sheriff's Office, 585 F. Supp. 2d 844 (W.D. Va. 2008); Goodwin v. MTD Products, Inc., 232 F.3d 600 (7th Cir. 2000). Here, Dr. Lipsey is neither a licensed doctor nor went to medical school. Dr. Lipsey Depo. at 16:25 – 17:1-5. Moreover, he acknowledges that he is not qualified to give medical opinions. Id. at 13:25 – 14:1-2. Yet, he tries to circumvent his lack of qualifications by saying that he does not “diagnose” the plaintiffs’ conditions, only that their symptoms are consistent with chronic exposure. Id. at 17:7-13. Relating plaintiffs' symptoms to those that result from mold exposure is a causation opinion. Undeniably, Dr. Lipsey is not qualified to render such an opinion.

In addition to his medical causation opinion, Dr. Lipsey opines that the subject house had “undoubtedly, mycotoxins.” Lipsey Report attached hereto as Exhibit L. He indicated that *Stachybotrys* always produces mycotoxins when there is a significant amount of moisture present. Dr. Lipsey Depo. at 31:17-22; 32:19-25 – 33:1-3. Despite this assertion, Dr. Lipsey admitted that there was no proof of the conditions in the home that enables mycotoxins to be present. Id. Not only is there an absence of this factual predicate, but he also admits that there was no testing of the house to determine the existence of mycotoxins. Id. at 33:1-3; 40:2-10. He

further admitted that he could not determine whether the plaintiffs were exposed to mycotoxins in the absence of any testing. Id. at 35:21-25 – 36:1-6; 40:2-10. Similarly, he acknowledges that there is no evidence that the children inhaled mycotoxins. Id. at 38:5-13. Moreover, there is no evidence that the plaintiffs were exposed to mycotoxins by any other means of exposure. Because these opinions are so lacking in a factual basis, Dr. Lipsey, or any expert for that matter, should not be permitted to opine about mycotoxins.

For his last opinion, Dr. Lipsey states that VOCs were present in the home based solely upon the Sci-Labs report of “heavy” *Stachybotrys* concentrations. Id. at 54:24-25 – 26:1. In essence, Dr. Lipsey is relying on another expert’s qualitative assessment that there were “heavy” concentrations. The reason he makes this analytically flawed opinion is because the subject house was not tested for VOCs. Id. at 55:1-10. Therefore, nobody knows the amount of the VOC exposure.

In the absence of any definitive testing, Dr. Lipsey offers an opinion based solely on his experience which is irrelevant to the amount of VOCs actually, if any, in the home. His opinion is unreliable for a number of reasons. First, the laboratory, which indicated “heavy”, did not count the spores, but made only a qualitative assessment. Id. at 73:18-20. In other words, this assessment is merely an opinion. Second, Dr. Lipsey said that the laboratory could have grown the spores in an incubator to determine the levels of *Stachybotrys* in a pure concentration, but it did not do so. Id. at 73:21-25. If the spores had been grown out, Dr. Lipsey claims that 300,000 *Stachybotrys* spores per gram of dust can be harmful. Id. at 74:7-11. Without such evidence, the opinion is purely speculative. Moreover, these self-created guidelines have not been published and are unfounded. Id. at 75:3-7. They are based only on Dr. Lipsey’s subjective opinion, which has not been published and not been peer reviewed. Id. at 75:11-13. Like Dr. Vance, Dr.

Lipsey is saying that VOCs were in the home “because he said so.” This type of opinion has been severely criticized in General Electric and Holesapple. See 522 U.S. at 146; 2001 U.S. App. LEXIS at 2.

It is quite clear that Dr. Lipsey’s own methodology that VOCs were in the house cannot be tested or proven, does not have a known potential rate of error, does not have standards controlling the operation, has not been subjected to peer review, and does not enjoy “general acceptance” within the scientific community.

In sum, no evidence exists that the levels of *Stachybotrys* was high due to the absence of any published data on safe or harmful levels of mold (*Stachybotrys*, etc.), no evidence that VOCs were present in the home, no evidence that the level of VOCs surpassed any acceptable limit, and no evidence that the plaintiffs were exposed to VOCs. For this reason, Dr. Lipsey’s opinion that the plaintiffs’ were exposed to high levels of VOCs is unfounded and highly unreliable.

IV. Dr. Elizabeth Frye’s Opinions are Unreliable and Irrelevant

Dr. Elizabeth Frye examined and treated the plaintiffs based solely upon the alleged exposure reported by Susan Kristensen. Frye Depo. at 31:1-4 attached hereto as Exhibit M. Defendants anticipate that the plaintiffs will offer Dr. Frye to prove that mold exposure caused their alleged symptoms. A treating physician is subjected to the same analysis under Rule 702 and Daubert to ensure the reliability and relevance of the opinion testimony. Perkins v. United States, 626 F. Supp. 2d 587, 592 (E.D. Va. 2009). A treating physician is not insulated from a traditional examination of reliability. Id. (“the plain language of the Daubert decision extends the threshold requirement of reliability to “any and all” medical testimony, including that of treating physicians.”). See also Turner v. Iowa Fire Equip. Co., 229 F.3d 1202, 1207 (8th Cir. 2000).

In Perkins, the court excluded the treating physician's causation opinion because the treating physician (i) took plaintiff's word on causation, (ii) did not adequately investigate the relevant medical history, and (iii) failed to consider alternative explanations for the plaintiff's injuries. Perkins, 626 F. Supp. 2d at 592-94. The court stated that the plaintiff failed to establish the reliability of the treating physician's opinions under the factors set forth in Daubert and its progeny. Id. By relying upon plaintiff's own causation theory, the treating physician did not exercise "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Id. at 593. In addition, the physician failed to consider "a wealth of important information," such as prior medical history, in making conclusions on the causation of the plaintiff's injuries. Id. at 594. Also, the treating physician failed to consider alternative explanations and failed to explain how he ruled out other causes when conducting a differential diagnosis. Id.

The case here is remarkably similar to that of Perkins and Dr. Frye's opinions should be excluded. Dr. Frye's causation opinion should be excluded for several reasons. First, like in Perkins, Dr. Frye essentially takes the Kristensen family's theory of causation and adopts it as her own. Dr. Frye relied solely upon statements by the family that mold was in the home. Frye Depo. at 32:1-4. She never saw any proof that mold was in the home. Id. at 21:15-22. She does not recall seeing any tests. Id. She even acknowledges that mold is ubiquitous. Id. At 22:13-15. Yet, she is unaware if there is any published data that indicates whether there is a safe level of mold exposure. Id. at 23:9-12. Dr. Frye did not "employ in [litigation] the same level of intellectual rigor that characterizes the practice of an expert in the relevant field" because she (i) took the reports of mold at face value and (ii) received no evidence of dangerous level of mold exposure. See Kumho, 526 U.S. At 152.

Second, similar to the case in Perkins, Dr. Frye failed to investigate a necessary part of the level of mold exposure. As indicated above, Dr. Frye was unaware of the level of mold exposure and was unaware of whether any published data exists to define acceptable exposure limits. The foundation upon which she rendered her opinion is purely speculative and not supported by a reliable evidentiary basis. In re Bausch & Lomb, Inc., 2009 U.S. Dist. LEXIS 83849. In fact, that explains why, in her letter dated May 6, 2002, that she stated “[the plaintiffs] have had multiple illnesses throughout this year possibly related to the [mold].” See Dr. Frye Letter attached hereto as Exhibit N (emphasis added). In addition, she states that the plaintiffs’ problems are “related to” the mold exposure. Id. Both “possibly related” and “related to” are not synonymous with “caused.” She testified in her deposition repeatedly that she cannot say that the mold “caused” the plaintiffs symptoms. Frye Depo. at 30:4-21, 31:16-19. At one point, she even acknowledged that she was speculating to the cause. Id. at 49:13-16. Dr. Frye’s opinion is squarely predicated upon guesswork and speculation.

Third, Dr. Frye failed to consider other explanations for the plaintiffs’ injuries, particularly for Alexander. According to Dr. Frye, Kaia first presented to her complaining of coughing and nasal congestion. Id. at 15:4-6. Alexander presented to Dr. Frye with complaints of upper respiratory infection symptoms, congestion, cough, low-grade fevers, irritability, decreased appetite, and history of multiple ear infections. Id. at 9-13. Dr. Frye admitted that, as part of her diagnosis, she never considered whether Alexanders’ problems were unrelated to mold. Id. at 36:21-22 – 37:1. She never considered whether Alexander had an autoimmune disease. Id. at 35:11-14. It is clear that Dr. Frye took the family's theory of causation.

The Court in Perkins instructs that the failure to take into account other potential causes as part of a differential diagnosis may be so lacking that it is unreliable for purposes of causation.

626 F. Supp. 2d at 592. A district court is justified for excluding the testimony when the expert fails to consider possible alternatives or to offer an explanation why the proffered alternative was not the sole cause. Id.

Dr. Frye acknowledged that an autoimmune disease manifests in the following symptoms: (1) susceptibility to infections, (2) frequent colds, (3) ear infections, (4) sore throat, (5) sinus problems, (6) recurrent headaches, and (7) low grade fevers. As later discovered, Dr. Saulsbury from UVA diagnosed Alexander with an autoimmune disease. Although these symptoms are almost identical to those complained of during Alexander's visit, Dr. Frye utterly failed to take into account any problem other than mold exposure. In short, she failed to consider alternative explanations as required in Claar and Perkins. As cautioned by the court in Perkins, Dr. Frye has engaged in "willful blindness" in rendering her causation opinion.

Fourth, the absence of any published data upon which Dr. Frye can rely to prove that the defendants were exposed to harmful levels of mold further supports exclusion because her theory (i) has not been subjected to peer review and publication and (ii) has not enjoyed "general acceptance" within the medical and scientific community.

Last, Dr. Frye fails to render a proper causation analysis of based upon a generally accepted causation criteria, like the *Bradford-Hill* formula. Like Dr. Vilseck, Dr. Frye failed to fully consider all of the factors. She, like Vilseck, failed to analyze factors such as timing, duration, exposure or dose in relationship to the various health triggering sources or agents when making her causation assessment.

For these reasons, Dr. Frye's opinions are founded upon speculation and adopting the family's theory of causation.

V. Dr. Andrew Elgort's Opinions are Irrelevant

Defendants believe that the plaintiffs will offer the testimony of Dr. Andrew Elgort, a licensed clinical psychologist, to show that Kaia's behavioral issues and emotional distress were caused by mold exposure. Dr. Elgort stated that Kaia originally presented to his office because "the parents were going through a divorce." Id. at 12:1-3. His work focused only on helping Kaia efficiently manage her behavior and adjust to the parents' divorce. Id. at 13:8-12. After examining Kaia, he stated that she suffers from an adjustment disorder not otherwise specified. Dr. Elgort Depo. at 13:16-19 attached hereto as Exhibit O. He further said that his "work had nothing to do with medical issues resulting from mold toxicity" and that mold was mentioned only "in passing." Id. at 12:17-18, 13:12-13. Clearly, any adjustment and psychological issues, according to Dr. Elgort, stem from the divorce and not the alleged mold exposure. Therefore, under Rule 702 and Rule 402 of the Federal Rules of Evidence, Dr. Elgort's testimony must be excluded as irrelevant and that it cannot be applied to the facts of this case.

WHEREFORE, the defendants respectfully request that this Court enter an Order to

- (i) Exclude the expert opinions of Dr. Leonard Vance, Dr. Joseph Vilseck, Dr. Richard Lipsey, Dr. Elizabeth Frye, and Dr. Andrew Elgort; and
- (ii) for such other and further relief as this Court deems appropriate.

Respectfully submitted,

WILLIAM DAVID SPOTNITZ
DENISE CONSTANCE SCHAIN

By s/ Chad A. Mooney
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CERTIFICATE OF SERVICE

I, Chad A. Mooney, do hereby certify that the foregoing **Defendants' Memorandum in Support of Motion in Limine to Exclude Dr. Leonard Vance, Dr. Joseph Vilseck, Dr. Richard Lipsey, Dr. Elizabeth Frye, and Dr. Andrew Elgort** was sent using the CM/ECF system which will send notification of such filing to David Bailey, counsel for plaintiff, on this 20th_ day of July, 2011.

s/ Chad A. Mooney
Chad A. Mooney